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CASE PR/4-30970A



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE PATENT OF

CUENOUD ET AL.

U.S. PATENT NO.: 6,878,721

ISSUED: APRIL 12, 2005

FOR: BETA2-ADRENOCEPTOR AGONISTS

Mail Stop Petition
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

REQUEST FOR RECONSIDERATION OF "FINAL" PATENT TERM ADJUSTMENT
UNDER 37 CFR 1.705(d)

Sir:

Patentees hereby respectfully request that the "final" Patent Term Adjustment (PTA) for USP 6,878,721 be corrected to 130 days under 37 CFR 1.705(d). The "cover" page of USP 6,878,721, a copy of which is attached, incorrectly lists 94 days.

Since the U.S. Patent and Trademark Office (PTO) did not send out an "initial" Office Action within 14 months of January 8, 2002, i.e., the day that the 35 U.S.C. §371 requirements were fulfilled and, therefore, did not comply with the requirement of 37 CFR 1.703(a)(1), but otherwise complied with the requirement of 37 CFR 1.703(a)(2), and since the patentees did not fail to engage in reasonable efforts to conclude prosecution of the application and, therefore, complied with the requirement of 37 CFR 1.704(b), the "initial" PTA was 81 days.

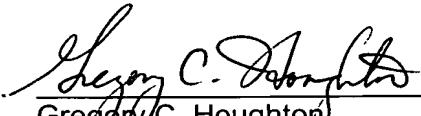
On the other hand, although the subject U.S. patent issued within 4 months of the date that the Issue Fee was paid and, therefore, the PTO complied with the requirement of 37 CFR 1.703(a)(6), it did not issue within 3 years from the date that the national stage commenced under 35 U.S.C. §371(b) and, therefore, the requirement of 37 CFR 1.703(b) was not complied with. Moreover, it appears that the PTO inadvertently calculated the "3-year" anniversary date from the date that the 35 U.S.C. §371 requirements were fulfilled, viz., January 8, 2002, rather than May 26, 2005, as evidenced by the AWONDAF2 0000003 190134 6878721.

than from the date that the national stage commenced, *viz.*, December 3, 2001. In this connection, and with regard to the "national stage" of PCT applications, the PTO 14-month rule contrasts with the PTO 3-year issue guarantee (see the attached appropriate highlighted section of the M.P.E.P.). Accordingly, instead of generating a credit of 130 days, the PTO's calculation incorrectly generated a credit of only 94 days.

In view of the foregoing, and since 37 CFR 1.703(f) precludes overlap beyond the actual number of days that the issuance of the subject U.S. patent was delayed, it is respectfully requested that this Request for Reconsideration be favorably considered and the "cover" page of the subject U.S. patent be corrected to reflect a "final" patent term adjustment of 130 days.

Please charge the \$200 fee required by 37 CFR 1.18(e) and any other fees that may be required to Deposit Account No. 19-0134 in the name of Novartis Corporation. An additional copy of this Request for Reconsideration of "final" PTA is enclosed.

Respectfully submitted,



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Attachs.: "cover" page of USP 6,878,721
highlighted sections of M.P.E.P.
extra copy of Request for Reconsideration
postcard

Date: May 24, 2005



US006878721B1

(12) **United States Patent**
Cuenoud et al.

(10) **Patent No.:** US 6,878,721 B1
(45) **Date of Patent:** Apr. 12, 2005

(54) **BETA2-ADRENOCEPTOR AGONISTS**

(75) Inventors: **Bernard Cuenoud**, Horsham (GB); **Ian Bruce**, Horsham (GB); **Robin Alec Fairhurst**, Horsham (GB); **David Beattie**, Horsham (GB)

(73) Assignee: **Novartis AG**, Basel (CH)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 94 days.

(21) Appl. No.: **10/009,008**

(22) PCT Filed: **Jun. 2, 2000**

(86) PCT No.: **PCT/EP00/05058**

§ 371 (c)(1),
(2), (4) Date: **Jan. 8, 2002**

(87) PCT Pub. No.: **WO00/75114**

PCT Pub. Date: **Dec. 14, 2000**

(30) **Foreign Application Priority Data**

Jun. 4, 1999 (GB) 9913083

(51) Int. Cl.⁷ **C07D 215/26; C07D 215/22; C07D 405/12; A61K 31/395; A61P 43/00**

(52) U.S. Cl. **514/312; 514/605; 514/649; 514/657; 546/157; 564/99; 564/123; 564/355; 564/360**

(58) Field of Search **514/312, 605, 514/649, 657; 546/157; 564/99, 123, 355, 360**

(56) **References Cited**

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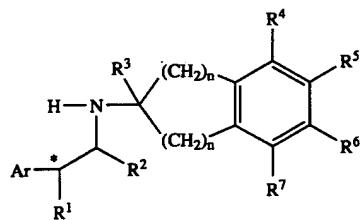
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Primary Examiner—Bruck Kifle

(74) Attorney, Agent, or Firm—Gregory C. Houghton

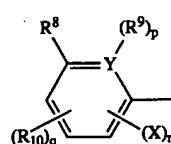
(57) **ABSTRACT**

Compounds of formula



in free or salt or solvate form, where

Ar is a group of formula



Y is carbon or nitrogen and R¹, R², R³, R⁴, R⁵, R⁶, R⁷, R⁸, R⁹, R¹⁰, X, n, p, q and r are as defined in the specification, their preparation and their use as pharmaceuticals, particularly for the treatment of obstructive or inflammatory airways diseases.

19 Claims, No Drawings

ending on the date of the termination of the suspension.

(2) The period of delay under paragraph (a)(2) of this section for an application is the sum of the following periods, to the extent that the periods are not overlapping:

(i) The number of days, if any, the application was maintained in a sealed condition under 35 U.S.C. 181;

(ii) The number of days, if any, in the period beginning on the date of mailing of an examiner's answer under § 1.193 in the application under secrecy order and ending on the date the secrecy order and any renewal thereof was removed;

(iii) The number of days, if any, in the period beginning on the date applicant was notified that an interference would be declared but for the secrecy order and ending on the date the secrecy order and any renewal thereof was removed; and

(iv) The number of days, if any, in the period beginning on the date of notification under § 5.3(c) and ending on the date of mailing of the notice of allowance under § 1.311.

(3) The period of delay under paragraph (a)(3) of this section is the sum of the number of days, if any, in the period beginning on the date on which an appeal to the Board of Patent Appeals and Interferences was filed under 35 U.S.C. 134 and ending on the date of a final decision in favor of the applicant by the Board of Patent Appeals and Interferences or by a Federal court in an appeal under 35 U.S.C. 141 or a civil action under 35 U.S.C. 145.

(d) The period of delay set forth in paragraph (c)(3) shall be reduced by:

(1) Any time during the period of appellate review that occurred before three years from the filing of the first national application for patent presented for examination; and

(2) Any time during the period of appellate review, as determined by the Director, during which the applicant for patent did not act with due diligence. In determining the due diligence of an applicant, the Director may examine the facts and circumstances of the applicant's actions during the period of appellate review to determine whether the applicant exhibited that degree of timeliness as may reasonably be expected from, and which is ordinarily exercised by, a person during a period of appellate review.

(e) The provisions of this section apply only to original patents, except for design patents, issued on applications filed on or after June 8, 1995, and before May 29, 2000.

[Added, 60 FR 20195, Apr. 25, 1995, effective June 8, 1995; para. (e) added, 65 FR 56366, Sept. 18, 2000, effective Oct. 18, 2000; para. (d)(2) revised, 68 FR 14332, Mar. 25, 2003, effective May 1, 2003; para. (a)(3) revised, 69 FR 21704, Apr. 22, 2004, effective May 24, 2004]

§ 1.702 Grounds for adjustment of patent term due to examination delay under the Patent Term Guarantee Act of 1999 (original applications, other than designs, filed on or after May 29, 2000).

(a) *Failure to take certain actions within specified time frames.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to:

(1) Mail at least one of a notification under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151 not later than fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 in an international application;

(2) Respond to a reply under 35 U.S.C. 132 or to an appeal taken under 35 U.S.C. 134 not later than four months after the date on which the reply was filed or the appeal was taken;

(3) Act on an application not later than four months after the date of a decision by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or 135 or a decision by a Federal court under 35 U.S.C. 141, 145, or 146 where at least one allowable claim remains in the application; or

(4) Issue a patent not later than four months after the date on which the issue fee was paid under 35 U.S.C. 151 and all outstanding requirements were satisfied.

(b) *Failure to issue a patent within three years of the actual filing date of the application.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the failure of the Office to issue a patent within three years after the date on which the application was filed under 35 U.S.C. 111(a) or the national stage commenced

under 35 U.S.C. 371(b) or (f) in an international application, but not including:

- (1) Any time consumed by continued examination of the application under 35 U.S.C. 132(b);
- (2) Any time consumed by an interference proceeding under 35 U.S.C. 135(a);
- (3) Any time consumed by the imposition of a secrecy order under 35 U.S.C. 181;
- (4) Any time consumed by review by the Board of Patent Appeals and Interferences or a Federal court; or
- (5) Any delay in the processing of the application by the Office that was requested by the applicant.

(c) *Delays caused by interference proceedings.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to interference proceedings under 35 U.S.C. 135(a).

(d) *Delays caused by secrecy order.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to the application being placed under a secrecy order under 35 U.S.C. 181.

(e) *Delays caused by successful appellate review.* Subject to the provisions of 35 U.S.C. 154(b) and this subpart, the term of an original patent shall be adjusted if the issuance of the patent was delayed due to review by the Board of Patent Appeals and Interferences under 35 U.S.C. 134 or by a Federal court under 35 U.S.C. 141 or 145, if the patent was issued under a decision in the review reversing an adverse determination of patentability. If an application is remanded by a panel of the Board of Patent Appeals and Interferences and the remand is the last action by a panel of the Board of Patent Appeals and Interferences prior to the mailing of a notice of allowance under 35 U.S.C. 151 in the application, the remand shall be considered a decision by the Board of Patent Appeals and Interferences as that phrase is used in 35 U.S.C. 154(b)(1)(A)(iii), a decision in the review reversing an adverse determination of patentability as that phrase is used in 35 U.S.C. 154(b)(1)(C)(iii), and a final decision in favor of the applicant under § 1.703(e). A remand by a panel of the Board of Patent Appeals and Interferences shall not be considered a decision in the review reversing an adverse determi-

nation of patentability as provided in this paragraph if there is filed a request for continued examination under 35 U.S.C. 132(b) that was not first preceded by the mailing, after such remand, of at least one of an action under 35 U.S.C. 132 or a notice of allowance under 35 U.S.C. 151.

(f) The provisions of this section and §§ 1.703 through 1.705 apply only to original applications, except applications for a design patent, filed on or after May 29, 2000, and patents issued on such applications.

[Added, 65 FR 56366, Sept. 18, 2000, effective Oct. 18, 2000; para. (e) revised, 69 FR 21704, Apr. 22, 2004, effective May 24, 2004]

§ 1.703 Period of adjustment of patent term due to examination delay.

(a) The period of adjustment under § 1.702(a) is the sum of the following periods:

(1) The number of days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) or fulfilled the requirements of 35 U.S.C. 371 and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(2) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply under § 1.111 was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(3) The number of days, if any, in the period beginning on the day after the date that is four months after the date a reply in compliance with § 1.113(c) was filed and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(4) The number of days, if any, in the period beginning on the day after the date that is four months after the date an appeal brief in compliance with § 1.192 was filed and ending on the date of mailing of any of an examiner's answer under § 1.193, an action under 35 U.S.C. 132; or a notice of allowance under 35 U.S.C. 151, whichever occurs first;

(5) The number of days, if any, in the period beginning on the day after the date that is four months